

**UNITED STATES DISTRICT COURT FOR THE  
DISTRICT OF NEW JERSEY**

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UNITED STATES OF AMERICA *ex rel.*  
LAURIE SIMPSON

Honorable John Michael Vazquez  
United States District Judge

*Plaintiff,*

Honorable Joseph A. Dickson  
United States Magistrate Judge

v.

BAYER CORPORATION;  
BAYER HEALTHCARE  
PHARMACEUTICALS, INC.;  
BAYER HEALTHCARE LLC; and  
BAYER AG,

Civil. No. 05-3895

*Defendants.*

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**UNITED STATES REPLY BRIEF IN SUPPORT OF APPEAL  
OF THE SPECIAL MASTER'S AUGUST 24, 2020 ORDER  
AND OPINION DENYING RELIEF PURSUANT TO  
FED. R. CIV. P. 45(d)(1) AND 45(d)(2)(B)(ii)**

**PRELIMINARY STATEMENT**

For almost an entire year, Bayer placed the Centers for Medicare and Medicaid Services (CMS), a non-party to this action, in an untenable position: produce almost 700 million pages of old and irrelevant paper records contained in 275,000 boxes at a cost of \$70 million to the Federal Government or dismiss the relator's case or sign what CMS viewed to be an inaccurate stipulation intended to advance Bayer's litigating position. As a direct result of CMS's *compliance with*

*Bayer's subpoena*, the agency lost almost \$3 million in funds committed to disposal contracts and incurred over \$300,000 in unnecessary storage expense.

In its opening brief, the United States identified four reasons why the Special Master's denial of the Government's request to shift a portion of these costs to Bayer constituted clear error, an abuse of discretion, or was contrary to law. *See* ECF No. 378-1 ("Government's Opening Br."). In its Response, Bayer fails to address any of these reasons. First, Bayer fails to explain how its insistence on almost 700 million pages of irrelevant aged paper records constitutes "normal advocacy" instead of an abuse of its subpoena power. Second, regardless of the number of meet-and-confers, Bayer fails to explain why it refused CMS's repeated requests to narrow the subpoena or why it rejected less burdensome alternatives to the paper records. Third, having failed its duty to take "reasonable steps to avoid imposing undue burden or expense," Bayer disregards the plain language of Rule 45(d)(1), which provides that a court "must enforce this duty and impose an appropriate sanction . . . on a party who fails to comply." Finally, Bayer makes no attempt to address clear case authority that a subpoena issued by a lawyer as an officer of the court is a court order within the meaning of Rule 45(d)(2)(B)(ii).

Accordingly, the United States respectfully requests that the Court vacate the Special Master's August 24, 2020 Order and Opinion and grant the Government's

request to shift to Bayer a portion of the costs CMS incurred in complying with Bayer's subpoena.

### **ARGUMENT**

#### A. Bayer Fails to Address the Egregious Circumstances of This Case Including the Breadth and Burden of its Subpoena.

As noted in the Government's opening brief, when considering an application for relief under Fed. R. Civ. 45(d)(1), "a court must conduct a two-part inquiry to determine: (1) whether the challenged subpoena imposed an undue burden or expense on the person(s) subject thereto; and (2) if so, what if any, 'reasonable steps' the subpoenaing party and its counsel took to avoid imposing such a burden[.]" *Saint-Jean v. Emigrant Mortgage Co.*, 11-CV-2122, 2015 WL 13735434, at \*3 (E.D.N.Y. Oct. 7, 2015) ("*Saint-Jean*"). In this case, the Special Master erred by failing to address both prongs. The Special Master did not take into account the egregious circumstances of this case, including the breadth, undue burden, and expense of Bayer's subpoena. As applied to the aged paper records issue, Bayer's subpoena would have required CMS to produce 687 million pages of aged paper records in 275,000 boxes at an estimated cost of \$70 million, all while diverting critical resources from CMS's primary public health mission. *See* Government's Opening Br. at 20-23. The Special Master also failed to address Bayer's refusal to narrow the subpoena or offer any reasonable steps to alleviate its burden. In fact,

the only choice that Bayer offered to CMS was for the Government to dismiss the relator's action or to sign a stipulation that CMS regarded as inaccurate.

1. Bayer's Subpoena to CMS Was Not Aimed at Understanding CMS's Payment Decisions.

In its Response, Bayer fails to explain how the breadth, burden, and expense of its subpoena to CMS constitutes "normal advocacy" instead of a misuse of its subpoena power.<sup>1</sup> Although Bayer claims that its subpoena was aimed at understanding CMS's payment decisions and processes, *see* ECF No. 382 ("Bayer Resp."), at 3, 13, the documented record contradicts Bayer's proffered justification.

In granting the Government's motion to quash, the Special Master found that the aged paper records were "outside the discovery period and not relevant to Bayer's claims." *See* ECF No. 378-12, at 11 (Order and Opinion of the Special Master dated March 26, 2020 ("SM Order Granting Mot. Quash")). He further

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<sup>1</sup> In a footnote, Bayer asserts that the Government forfeited its right to seek costs and did not give notice of its intention to seek costs. *See* ECF No. 382, at 11, n.5. Bayer's arguments are meritless. First, as to Bayer's claimed lack of notice, CMS objected to Bayer's subpoena under Rule 45(d)(2)(B), provided Bayer with a detailed memorandum about the undue burden and expense of the subpoena, notified Bayer that it would seek costs, and moved to quash. *See* ECF No. 363-4, Exhibit 3, attached to Motion to Quash (Cover Email from Eden Heard to James Perez dated July 16, 2019). This case is unlike *Lee v. Virginia State Board of Elections*, 2016 WL 6915308 (E.D.Va. Sep. 2, 2016), where the Court denied costs because the non-party voluntarily complied with the subpoena and later sought costs "as a *post hoc* protection from the burdens of compliance with Plaintiff's subpoena." *Id.* at \*2. Second, while the Government could have requested cost shifting in a separate filing, it was not required to do so. The Government requested cost shifting in the same letter brief as its opposition to Bayer's motion for reconsideration because both issues concerned the same underlying facts, increasing efficiencies for the parties and the court.

characterized review of the aged paper records to be “a fishing expedition” and concluded that the boxes were a “continuing burden” for CMS to maintain. *See id.*

Bayer also knew that the aged paper records consisted mostly of “as submitted” paper claims that *lacked actual payment decisions*. Therefore, the aged paper records could not possibly provide an understanding of CMS’s payment decisions. In fact, CMS offered to produce electronic claims data from its National Claims History Database, which contained payment decisions. The electronic claims data is far “more convenient, less burdensome, and less expensive” to produce than the paper claims. *See Fed. R. Civ. P. 26(b)(2)(C)(i)*. CMS even invited Bayer to collaborate with the relator on a joint request for electronic claims data and to share the costs, but Bayer rejected that invitation.

In its Response, Bayer fails to explain why it rejected collaboration with the relator, why it refused the electronic claims data, and why it would not alter its demand for paper records with no payment decisions. In fact, the Special Master highlighted this failure when granting the Government’s motion to quash:

*Bayer has failed to explain why the information in the National Claims History database is inadequate and why the paper records themselves must be provided. Any relevancy arguments are further suspect in light of the fact that the aged paper records do not include information related to payment decision on the claims. It is difficult to ascertain how Bayer could “learn whether the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the two legal requirements at issue” when payment decision are not included within the aged paper records.*

SM Order Granting Mot. Quash at 11 (emphasis added). This failure underscores that Bayer had no genuine interest in, or need for, the hundreds of millions of pages of irrelevant aged paper records that it demanded CMS produce at great burden and expense to the taxpayer.

2. Bayer Did Not Offer Any Reasonable Alternatives to CMS During the Meet and Confer Process.

Bayer claims that it “made good-faith, reasonable efforts to reduce any purported burden on the Government” and that it participated in multiple meet-and-confers. Bayer Resp. at 13. Bayer’s “good-faith, reasonable efforts” were, however, illusory and self-serving. Those efforts consisted of suggesting that the Government exercise its authority under 31 U.S.C. § 3729(c)(2)(A) to dismiss the relator’s case, mooted Bayer’s need for further discovery. *See* ECF No. 363-7, at 3. Alternatively, CMS could sign a stipulation the agency viewed to be inaccurate. Bayer gave CMS no other choice. It rejected every option offered by CMS and refused to narrow its subpoena in any way.<sup>2</sup>

Neither of Bayer’s alternatives qualify as a reasonable step to avoid imposing undue burden and expense under Rule 45(d)(1). Bayer makes no attempt to defend

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<sup>2</sup> Bayer seeks to justify its conduct by raising the issue of boxes of unknown date. *See* Bayer Resp. at 8, 15. This issue is a red-herring. The Government’s motion to quash sought relief only with respect to “aged paper records dating *from 1996 to 1999*,” and that was the scope of the relief granted by the Court. It did not request relief with respect to boxes of unknown date range or include them in its box count estimate in its motion to quash.

the use of a facially overbroad subpoena to leverage a dismissal, claiming that this characterization is “incorrect and unfair” and unintentional despite contemporaneous exchanges in which Bayer raised dismissal.

As for the stipulation, Bayer presented CMS with the same coercive choice: sign a stipulation that CMS viewed to be inaccurate<sup>3</sup> or retain and produce, hundreds of millions of pages of irrelevant aged paper records that Bayer never bothered to examine despite repeated offers by CMS to make a sample available. The Special Master rejected this alternative as a “viable means for reducing CMS’s burden”:

the Government has maintained that CMS absolutely cannot enter into Bayer’s requested stipulation because CMS could not make the representations Bayer sought to have affirmed. Being as it was impossible for CMS to enter into the proposed stipulation, *Bayer’s proposal was not in actuality a viable means for reducing CMS’s burden.*

ECF No. 376, at 5 (SM Order Denying Bayer’s Mot. for Recon.) (emphasis added).

### 3. Bayer Refused to Review a Sample of the Aged Paper Records During the Meet and Confer Process.

Bayer further suggests that it offered to sample the documents at its own cost, and claims that this “would have entirely relieved the Government of any possible burden.” *See* Bayer Resp. at 13. Bayer’s argument is incorrect. Before it filed its

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<sup>3</sup> During the meet and confer process, counsel for CMS repeatedly advised Bayer that any representation that “CMS has never denied payment” was not possible. Indeed, counsel for CMS do not possess the personal knowledge to make such a broad, binding, and unequivocal representation about every claim ever processed by Medicare.

motion to quash, CMS repeatedly offered Bayer the opportunity to review a sample of the aged paper records, in a good faith effort to show Bayer that they were irrelevant so that Bayer might agree to exclude them from the scope of the subpoena. CMS offered to make available a “significant sampling” of paper records that it would draw from multiple locations at a single facility to spare Bayer the expense of reviewing documents at multiple storage facilities around the country. Bayer refused this offer.

It was not until October 21, 2019, *almost three weeks after the Government filed its motion to quash*, that Bayer expressed for the first time a willingness to *consider* reviewing a sample. *See* ECF No. 373, at 6. Bayer did not actually agree to inspect a sample but imposed additional conditions on its willingness to do so. *See id.* Significantly, Bayer’s willingness to “consider” reviewing a sample, without any further agreement over the scope of the subpoena, did nothing to alleviate the burden and expense of Bayer’s subpoena, as Bayer could simply refuse to narrow the subpoena after reviewing the sample.

Having gone through the meet and confer process to no avail and having filed a motion to quash, there was no reason to believe that Bayer’s proposal was anything but an attempt to delay a disposition on the pending motion to quash. As one court observed when confronted with similar tactics, “to allow [Bayer] now to seek shelter from a fallback position that [the Government] previously tendered in good faith



would make a mockery of both parties' obligation to meet and confer in good faith from the start." *Bos. Sci. Corp. v. Lee*, No. 1:13-CV-13156-DJC, 2014 WL 3851157, at \*7 (N.D. Cal. Aug. 4, 2014).<sup>4</sup>

In sum, Bayer did not use its subpoena authority to seek information relevant to its defenses and proportional to the needs of the case. *See* Fed. R. Civ. P. 26(b)(1). Rather, Bayer used its subpoena authority to extract litigation concessions from the Government, a non-party in this matter. In order to maintain its leverage, Bayer refused to narrow its subpoena and refused less burdensome alternatives to the production of the incomplete and irrelevant aged paper records.

Although the Court could conclude that Bayer acted with an "improper purpose," such a finding is not necessary for relief under Fed. R. Civ. P. 45(d)(1). *See In re. Modern Plastics Corp.*, 890 F.3d 244, 251 (6th Cir. 2018) (rejecting a "bad faith requirement" as a prerequisite for the imposition of sanctions under Rule 45(d)(1)); *Legal Voice v. Stormans*, 738 F.3d 1178, 1186 (9th Cir. 2013). Regardless, of Bayer's motives, the objective circumstances of this case contain all of the factors that justified sanctions in other cases: 1) an indisputably broad and unduly burdensome subpoena for irrelevant documents; 2) a refusal to narrow or

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<sup>4</sup> The Special Master also rejected Bayer's belated offer to review a sample of the aged paper records as a proposal "that would relieve the Government of any burden." ECF No. 376, at 2, 5. The Special Master found that "Bayer's belated application. . . was not required to be accepted by the Government[.]" *Id.* at 5.

tailor the subpoena; and 3) a refusal to accept less burdensome alternatives. *See, e.g., In re Modern Plastics*, 890 F.3d at 251 (sanctions where expense could have been avoided by “tailor[ing] the document requests”); *Mattel, Inc. v. Walking Mountain Productions*, 353 F.3d 792 (9th Cir. 2003) (sanctions where subpoenas were not served “for the purpose of getting information”); *Saint-Jean*, 2015 WL 13735434, at \*5-6 (sanctions where information “could and should have been sought through less intrusive means”).

B. Rule 45(d)(1) is Intended to Compensate a Non-Party For Expenses Suffered as a Result of the Misuse of a Subpoena.

Bayer argues that, because the Government “produced nothing in response” from the boxes at issue, it suffered no cognizable cost or burden under Rule 45(d)(1). Bayer Resp. at 17-18. Bayer’s reading of Rule 45(d)(1), limiting cognizable costs or burdens to those resulting from the act of document production, is inconsistent with the plain language of the rule. In pertinent part, Rule 45(d)(1) provides that a court “must enforce this duty and impose an appropriate sanction – which may include lost earnings and reasonable attorney’s fees – on a party or attorney who fails to comply.” Fed. R. Civ. P. 45(d)(1). If Bayer’s interpretation were correct, then “lost earnings and reasonable attorney fees,” which are expressly contemplated by the rule, would not be cognizable because they are not document production costs.

Rather, as explained in the Government’s opening brief, Rule 45(d)(1) is intended to compensate a non-party for losses and expenses suffered because of a

breach of the underlying duty. *See Builders Ass’n of Greater Chicago v. City of Chicago*, 96-C-1122, 2002 WL 1008455, at \*6 (N.D. Ill. May 13, 2002) (“*Builders*”) (noting the “compensatory intention” of the Rule). Given its “compensatory intention,” as long as a non-party can demonstrate the loss resulted from a party’s failure to comply with its duty, there is no basis for arbitrary limits on the types of costs a court may award. *See Saint-Jean*, 2015 WL 13735434, at \*3 (Rule 45(d)(1) is “intended to protect a non-party witness as a result of misuse of the subpoena”).

Here, Bayer misused its subpoena authority by propounding a vastly overbroad subpoena and refusing to take any reasonable steps to reduce the resulting burden, as expressly required by Rule 45(d)(1). Until CMS could obtain relief from the Court, the agency had no choice but to comply with Bayer’s subpoena by suspending its pre-planned Archived Records Disposal Initiative or face contempt under Rule 45(g). As a direct consequence of its *compliance with Bayer’s subpoena*, CMS lost almost \$3 million in funds committed to disposal contracts and incurred over \$300,000 in unnecessary storage expense. *See* ECF No. 373-1 (Second Suppl. Decl. of Chris Klots). These are costs CMS would not have incurred but for its compliance with Bayer’s subpoena. Indeed, the Special Master specifically acknowledged, “the continuing burden on [CMS] as a result of maintaining these aged paper records that otherwise would be subject to the routine Aged Records Disposal Initiative.” SM Order Granting Mot. Quash, at 11.

The United States is not seeking to shift all the costs it incurred in complying with Bayer’s subpoena. The Government acknowledges that Rule 45(d)(1) permits the court to impose “an appropriate sanction” and thus accords discretion to the court in determining that sanction. But, in light of Bayer’s breach of its duty – a duty the court “must enforce” – it was an abuse of discretion for the Special Master to deny CMS the protections of cost shifting altogether. CMS should not have to bear the entire cost of its forced compliance with a vastly overbroad burdensome subpoena that Bayer could but refused to narrow. The United States requests a fair and proportional outcome, shifting to Bayer a portion of its subpoena compliance costs.

C. Rule 45(d)(2)(B)(ii) Provides an Alternative Basis For Cost Shifting Under the Circumstances of This Case.

Alternatively, the Government requested relief under Rule 45(d)(2)(B)(ii), which provides for “mandatory” cost shifting to protect a non-party from “significant expense resulting from compliance” with a subpoena. *R.J. Reynolds Tobacco v. Philip Morris, Inc.*, 29 F. App’x 880, 882 (3d Cir. 2002); *Linder v. Calero–Portocarrero*, 251 F.3d 178, 182 (D.C. Cir. 2001); *Legal Voice*, 738 F.3d at 1184. The Special Master denied relief under Rule 45(d)(2)(B)(ii), on the ground that he had not issued an order compelling CMS to comply with the subpoena.

In its Response, Bayer ignores the argument and case authority that a subpoena issued by a lawyer, as an officer of the court, is a court order within the meaning of Rule 45(d)(2)(B)(ii), that a non-party must obey subject to contempt

under Rule 45(g). *See* 1991 Advisory Committee Notes to Rule 45 (“defiance of a subpoena is nevertheless an act in defiance of a court order and exposes the defiant witness to contempt sanctions.”); *SEC v. Hyatt*, 621 F.3d 687, 693 (7th Cir. 2010); *Pennwalt Corp. v. Durand-Wayland, Inc.*, 708 F.2d 492, 494, n.5 (9th Cir. 1983). In this case, CMS objected to Bayer’s subpoena within 14 days of Bayer’s service of the subpoena pursuant to Rule 45(d)(2)(B). Therefore, it was not required to produce documents. CMS had no similar choice with respect to the *preservation* of documents responsive to the subpoena. Unless Bayer agreed to narrow its subpoena or until it could obtain judicial relief, CMS was required to comply with the subpoena by preserving the aged paper records. This forced CMS to suspend its pre-planned Archived Records Disposal Initiative or face contempt for disobeying the subpoena under Rule 45(g). It is in this regard that Bayer’s subpoena constitutes a court order within the meaning of the rule. As a direct consequence of its necessary *compliance with Bayer’s subpoena*, CMS incurred costs it would not have incurred but for the subpoena.<sup>5</sup> Bayer had every opportunity to avoid these costs by taking

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<sup>5</sup> Bayer’s argument that CMS has been storing the boxes for over twenty years is meritless. The Special Master specifically recognized “the *continuing burden* on [CMS] as a result of maintaining these paper records that would otherwise be subject to the routine Aged Records Disposal Initiative.” SM Order Granting Mot. Quash at 11 (emphasis added). Furthermore, the Special Master specifically found that “CMS is incurring a minimum of \$37,000 in monthly storage expenses for aged paper records that *would have been destroyed but for the subpoena hold*. Moreover, this expense is expected to increase by the end of May 2020 to \$70,000 in monthly storage expense.” *See id.* at 11-12 (emphasis added).

reasonable steps to narrow the subpoena. Bayer chose not to and should therefore assume some of the resulting costs.

Bayer argues that cost-shifting in this district requires a multi-factor analysis that was prevalent under a prior version of Rule 45. Bayer Resp. at 20.<sup>6</sup> These factors are obsolete and unsuited to the unique context of declined *qui tam* actions. When the United States declines to intervene in a *qui tam* action, it is a non-party for purposes of discovery. *United States ex rel. Eisenstein v. City of New York*, 556 U.S. 928 (2008). As the *Eisenstein* recognized, when the United States elects not to intervene, it also “decline[s] to assume the rights and burdens attendant to full party status,” including the burdens of discovery. *Id.* at 933-34. Application of the obsolete factors in a declined *qui tam* action, as Bayer argues, would effectively disqualify the United States from the protections of Rule 45. Without those protections, the Government would be at the mercy of defendants attempting to leverage dismissals with unduly broad and burdensome discovery demands.

Nevertheless, application of the multi-factor analysis should take account of the underlying circumstances, which plainly justify cost shifting in this case. *See McGraw-Hill*, 302 F.R.D. at 536, n.1 (applying cost shifting even though the case

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<sup>6</sup> The D.C. Circuit has recognized that this multi-factor analysis emerged from “pre-1991 cases dealing with cost-shifting” under the “old Rule 45(b), which gave district court’s *discretion* to condition the enforcement of subpoenas on the petitioners paying for the costs of production.” *Linder*, 251 F.3d at 182 (emphasis in original); *see also United States v. McGraw-Hill*, 302 F.R.D. 532, 535 (C.D. Ca. 2014) (expressing “doubt that these factors survive the 1991 amendment” and concluding after a detailed discussion that “the multi-factor analysis . . . is now obsolete”).

was of “notable public importance” and the non-parties are “not purely disinterested.”). Here, Bayer demanded hundreds of millions of pages of aged paper records that the Special Master found to be a “fishing expedition,” irrelevant to its defenses, and a “continuing burden” to maintain. Bayer’s conduct has caused CMS to lose contract funds and needlessly incur storage expense. Bayer should “bear at least enough of the expense to render the remainder ‘non-significant.’” *Linder*, 251 F.3d at 182; *R.J. Reynolds*, 29 F. App’x at 883 (“significant expenses must be borne by the party seeking discovery”).

### **CONCLUSION**

Accordingly, for the foregoing reasons, the United States respectfully requests that this court vacate the Special Master’s August 24, 2020 Order and Opinion, and grant the Government’s request for cost shifting pursuant to Fed. R. Civ. P. 45(d)(1), or alternatively, Fed. R. Civ. P. 45(d)(2)(B)(ii).

Dated October 15, 2020  
Newark, New Jersey

Respectfully submitted,

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